



IFW

Patent
45198.00016.DIV

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:

Applicant: Erion et al.

Serial No.: 10/780,948

Filed: February 17, 2004

**For: COMBINATION OF FBPase
INHIBITORS AND INSULIN
SENSITIZERS FOR THE TREATMENT
OF DIABETES**

)
) **Group Art Unit:** 1614

)
) **Examiner:** Not yet assigned.

TRANSMITTAL LETTER

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Sir:

Enclosed are the following documents:

- Information Disclosure Statement;
- Form PTO/SB/08A; and
- Return Postcard.

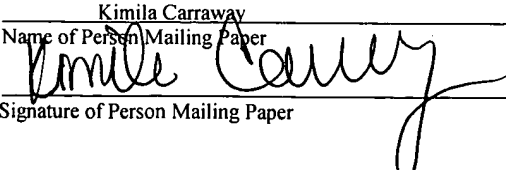
CERTIFICATE OF MAILING
(37 C.F.R. §1.8a)

I hereby certify that this paper (along with anything referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as First Class Mail in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

February 25, 2004
Date of Deposit

::ODMA\PCDOCS\SAN_DIEGO\90635\1
SAN /90635.1

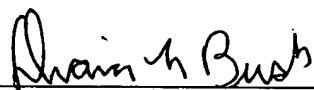
Kimila Carraway
Name of Person Mailing Paper


Signature of Person Mailing Paper

The Commissioner is authorized to charge any fee required, or to credit any overpayment, to our Deposit Account No. **50-2613**.

Respectfully submitted,

Dated: 5/20/04

By: 
Diana L. Bush, Ph.D., Esq.
Reg. No. 51,109

PAUL, HASTINGS, JANOFSKY & WALKER LLP

3579 Valley Centre Drive
San Diego, CA 92130-2081
Phone: (858) 720-2500
Fax: (858) 720-2555



Patent
45198.00016.DIV

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:

Applicant: Erion et al.

Serial No.: 10/780,948

Filed: February 17, 2004

**For: COMBINATION OF FBPase
INHIBITORS AND INSULIN
SENSITIZERS FOR THE TREATMENT
OF DIABETES**

)
) **Group Art Unit:** 1614

)
) **Examiner:** To Be Assigned

**INFORMATION DISCLOSURE STATEMENT UNDER
37 CFR § 1.97 (B)(3)**

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Sir:

In compliance with the Applicant's duty under 37 CFR § 1.56, the following information is brought to the attention of the Examiner. The items are listed on the attached form PTO-1449 and copies of the references have previously been submitted in the parent cases.

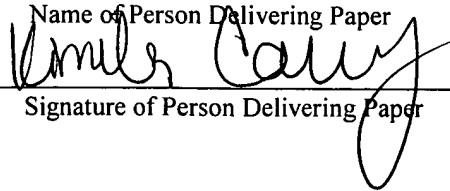
**CERTIFICATE OF MAILING
(37 CFR §1.8 a)**

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as First Class Mail in an envelope addressed to the Commissioner for Patents, Washington, D.C. 20231.

May 20, 2004
Date of Delivery
SAN /90534.1

Kimila Carraway

Name of Person Delivering Paper


Signature of Person Delivering Paper

The items identified in this Information Disclosure Statement (IDS) may or may not be "material" pursuant to 37 CFR § 1.56 and the submission thereof by Applicant shall not be construed as an admission that any such patent, publication or other information referred to therein is material or considered to be material (37 CFR § 1.97(h)), or even qualifies as "prior art" under 35 USC § 102 with respect to this invention unless specifically designated by Applicant as such.

The filing of this IDS shall not be construed to mean that a search has been made or that no other material information, as defined in 37 CFR § 1.56, exists.

The attached IDS is being filed in accordance with 37 CFR §§ 1.97 and 1.98. This IDS is believed to be timely in that it is being submitted under 37 CFR § 1.97(b)(3), that is before the mailing of a first Office Action on the merits. Thus, no petition or fee is required. However, if the undersigned representative of Applicant is in error in this regard, then the Examiner is requested to consider this IDS as filed under § 1.97(c) and is further authorized to charge any fee required by the filing of these papers to Paul, Hastings, Janofsky & Walker's Deposit Account No. **50-2613**.

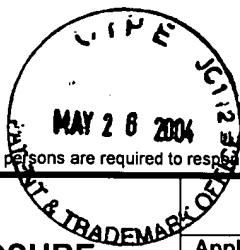
Respectfully submitted,

Dated: 5/20/04

By: Diana L. Bush
Diana L. Bush, Ph.D., Esq.
Reg. No. 51,109

PAUL, HASTINGS, JANOFSKY & WALKER, LLP
3579 Valley Centre Drive
San Diego, California 92130
Telephone: (858) 720-2500
Facsimile: (858) 720-2555

Please type a plus sign (+) inside this box → +



PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO

Complete if Known

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet	1	of	4	Application Number	10/780,948
				Filing Date	February 17, 2004
				First Named Inventor	Erion et al.
				Group Art Unit	1614
				Examiner Name	Not yet assigned
				Attorney Docket Number	45198.00016.DIV

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
		4,728,739		Kees et al.	03/01/88	
		4,791,125		Clark	12/13/88	
		4,968,790		De Vries et al.	11/06/90	
		5,236,941		Zask et al.	08/17/93	
		5,457,109		Antonucci et al.	10/10/95	
		5,468,762		Malamas et al.	11/21/95	
		5,478,853		Regnier et al.	12/26/95	
		5,532,256		Malamas et al.	07/02/96	
		5,658,889		Gruber et al.	08/19/97	
		6,028,052		Heyman et al.	02/22/00	
		6,200,998		Sahoo et al.	03/13/01	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Office ³	Number ⁴	Kind Code ⁵ (if known)				
		CA	2 173 660 A1		Kallam et al.	04/09/96		
		JP	07-002852 A2		Yoshioka et al.	01/06/95		
		EP	0 091 761 B1		Kawamatsu et al.	11/19/87		
		EP	0 129 747 A2		Hasler et al.	06/05/84		
		EP	0 177 353 A2		Meguro et al.	10/03/85		
		EP	0 283 035 A1		Iijima et al.	03/18/88		
		EP	0 427 799 B1		Gruber	01/24/90		
		EP	0 489 663 A1		Miyaoka et al.	12/06/91		
		EP	0 506 273 A2		Arita et al.	03/16/92		
		EP	0 543 662 A2		Fujita et al.	11/20/92		
		EP	0 559 571 A1		De nanteuil et al.	03/05/93		
		EP	0 708 098 A1		Yanagisawa et al.	10/09/95		
		EP	0 745 600 A1		Fujita et al.	12/04/96		
		EP	0 787 727 A1		Nagao et al.	08/06/97		

Examiner Signature SAN /90564.1

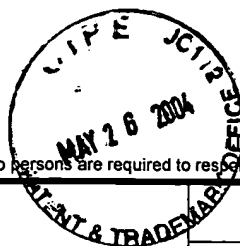
Date Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation is not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Please type a plus sign (+) inside this box → +



PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Complete if Known

Sheet	2	of	4	Application Number	10/780,948
				Filing Date	February 17, 2004
				First Named Inventor	Erion et al.
				Group Art Unit	1614
				Examiner Name	Not yet assigned
				Attorney Docket Number	45198.00016.DIV

	EP	0 861 666 A2		Ikeda et al.	09/02/98		
	WO	92/14719 A1		Ohnota et al.	09/03/92		
	WO	94/01433 A1		Shibata et al.	01/20/94		
	WO	95/026347 A1		Ohara et al.	10/05/95		
	WO	96/11196 A1		Ohara et al.	04/18/96		
	WO	96/26207 A1		Ohara et al.	08/29/96		
	WO	96/38427 A1		Yanagisawa et al.	12/05/96		
	WO	96/38428 A1		Maeda et al.	12/05/96		
	WO	96/39401 A1		Inman et al.	12/12/96		
	WO	97/10819		Heyman et al.	03/27/97		
	WO	97/37688 A2		Tamura et al.	10/16/97		
	WO	97/40051 A1		Takatani et al.	10/30/97		
	WO	98/39342 A1		Reddy et al.	09/11/98		
	WO	98/39343 A1		Kasibhatla et al.	09/11/98		
	WO	98/39344 A1		Dang et al.	09/11/98		

NON PATENT LITERATURE DOCUMENTS

Examiner Initials ¹	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		Amri et al., "Regulation of adipose cell differentiation. I. Fatty acids are inducers of the aP2 gene expression," <u>J. Lipid Res.</u> , 32:1449-1456 (1991).	
		Brown et al., "A novel N-aryl tyrosine activator of peroxisome proliferator-activated receptor-γ reverses the diabetic phenotype of the Zucker diabetic fatty rat," <u>Diabetes</u> , 48:1415-1424 (1999).	
		Clark et al., "Substituted dihydrobenzopyran and dihydrobenzofuran thiazolidine-2,4-diones as hypoglycemic agents," <u>J. Med. Chem.</u> , 34:319-325 (1991).	
		Folli et al., "Angiotensin II inhibits insulin signaling in aortic smooth muscle cells at multiple levels," <u>J. Clin. Invest.</u> , 100(9):2158-2169 (1997).	
		Fujiwara et al., "Characterization of new oral antidiabetic agent CS-045: Studies in KK and ob/ob mice and Zucker fatty rats," <u>Diabetes</u> , 37:1549-1558 (1988).	

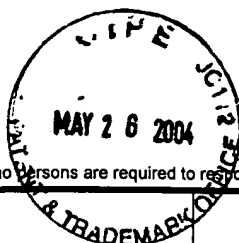
Examiner Signature	SAN /90564.1	Date Considered	
--------------------	--------------	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation is not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Please type a plus sign (+) inside this box → +



PTO/SB/08A (08-00)
Approved for use through 10/31/2002. OMB 0651-0031

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Application Number	10/780,948
		Filing Date	February 17, 2004
		First Named Inventor	Erion et al.
		Group Art Unit	1614
		Examiner Name	Not yet assigned
		Attorney Docket Number	45198.00016.DIV
Sheet	3	of	4

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		Glucksmann et al., "novel mutations and a mutational hotspot in the MODY3 gene," <u>Diabetes</u> , 46:1081-1086 (1997).	
		Grimaldi et al., "Induction of a P2 gene expression by nonmetabolized long-chain fatty acids," <u>Proc. Natl. Sci. USA</u> , 89:10930-10934 (1992).	
		Howard et al., "Insulin sensitivity and atherosclerosis," <u>Circulation</u> , 93(10):1809-1817 (1996).	
		Hulin et al., "Novel thiazolidine-2,4-diones as potent euglycemic agents," <u>J. Med. Chem.</u> , 35:1853-1864 (1992).	
		Lehmann et al., "An antidiabetic thiazolidinedione is a high affinity ligand for peroxisome proliferator-activated receptor gamma (PPAR gamma)," <u>J. Biol. Chem.</u> , 270(22):12953-6 (1995).	
		Maryanoff et al., "Stereoselective synthesis and biological activity of β - and α -D-arabinose 1,5-diphosphate: Analogues of a potent metabolic regulator," <u>J. Am. Chem. Soc.</u> , 106:7851-7853 (1984).	
		Mathisen et al., "The effect of pioglitazone on glucose control and lipid profile in patients with type 2 diabetes," <u>Diabetes</u> , 48(Suppl. 1):0441 (1998).	
		Patel et al. "Rosiglitazone monotherapy improves glycaemic control in patients with type 2 diabetes: A twelve-week, randomized, placebo-controlled study," <u>Diabetes, Obesity and Metabolism</u> , 1:165-172 (1999).	
		Riddle, "New tactics for type 2 diabetes: Regimens based on intermediate-acting insulin taken at bedtime," <u>The Lancet</u> , 192-195 (1985).	
		Saltiel & Olefsky, "Thiazolidinediones in the treatment of insulin resistance and type II diabetes," <u>Diabetes</u> , 45:1661-1669 (1996).	
		Scheen et al., "Oral antidiabetic agents: A guide to selection," <u>Drugs</u> , 55:225-236 (1998).	
		Schmitz-Peiffer et al., "Reversal of chronic alterations of skeletal muscle protein kinase C from fat-fed rats by BRL-49653," <u>Am. J. Physiol.</u> , 273:E915-E921 (1997).	
		Sreenan et al., "Prevention of hyperglycemia in the Zucker diabetic fatty rat by treatment with metformin or troglitazone," <u>Am. J. Physiol.</u> , 271:E742-747 (1996).	

Examiner Signature	SAN /90564.1	Date Considered	
--------------------	--------------	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation is not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Please type a plus sign (+) inside this box → +



PTO/SB/08A (08-00)
Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 4 of 4

Complete if Known

Application Number	10/780,948
Filing Date	February 17, 2004
First Named Inventor	Erion et al.
Group Art Unit	1614
Examiner Name	Not yet assigned
Attorney Docket Number	45198.00016.DIV

NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		Tontonoz et al., "Stimulation of Adipogenesis in fibroblasts by PPARγ2, a lipid-activated transcription factor," <u>Cell</u> , 79:1147-1159 (1994).	
		Tontonoz et al., "mPPARγ2: Tissue specific regulator of an adipocyte enhancer," <u>Gene and Development</u> , 8:1224-1234 (1994).	
		Torlone et al., "Improved insulin action and glycemic control after long-term angiotensin-converting enzyme inhibition in subjects with arterial hypertension and type II diabetes," <u>Diabetes Care</u> , 16(10):1347-1355 (1993).	
		U.K. prospective diabetes study group, "U.K. prospective diabetes study 16: Overview of 6 years' therapy of type II diabetes: A progressive disease," <u>Diabetes</u> , 44:1249-1258 (1995).	
		Valiquett et al., "Troglitazone dose-response study in patients with NIDDM," <u>Diabetes</u> , 44(Suppl. 1):406 (1995).	
		Willson et al., "The structure-activity relationship between peroxisome proliferators-activated receptor γ agonism and the antihyperglycemic activity of thiazolidinediones," <u>J. Med. Chem.</u> , 39:665-668 (1996).	
		Zask et al., "Synthesis and antihyperglycemic activity of novel 5-(naphthalenylsulfonyl)-2, 4-thiazolidinediones," <u>J. Med. Chem.</u> , 33:1418-1423 (1990).	
		<u>Diabetologia</u> , 36 (Suppl.):182A (1993).	
		<u>Diabetes</u> , 42 (Suppl.):79A (1993).	
		<u>Diabetes</u> , 45 (Suppl. 2):141A (1996).	

Examiner Signature SAN /90564.1

Date Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation is not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.